

**IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE**

IN RE:)
)
AREDIA® AND ZOMETA® PRODUCTS)
LIABILITY LITIGATION) No. 3:06-MD-1760
)
(MDL No. 1760)) JUDGE CAMPBELL
)
This Document Relates To Case No.:) MAGISTRATE JUDGE BROWN
)
3:08-CV-00216 (Messick))
)

**NOVARTIS PHARMACEUTICALS CORPORATION’S MEMORANDUM
IN SUPPORT OF *DAUBERT* MOTION TO EXCLUDE CAUSATION
TESTIMONY OF PLAINTIFF’S EXPERTS IN THE *MESSICK* CASE**

Plaintiff Linda Messick has designated Dr. Richard Jackson as a retained expert and Dr. Gary Cecchi, Dr. Herbert Fawcett, Dr. Pritchard Lam, Dr. Matthew Liautaud, and Dr. Sol Silverman as non-retained experts. Plaintiff's Rule 26(a)(2)(A) Statement ("Pl's Stmt.") (attached as Exhibit 1).¹ To the extent that plaintiff seeks to offer these individuals to present testimony that Aredia^{®2} or Zometa[®] caused Mrs. Messick to develop osteonecrosis of the jaw ("ONJ"), their testimony should be excluded under *Daubert v. Merrell Dow Pharmaceuticals*,

¹ Plaintiff requested that Dr. Said-Al-Naief perform a pathology analysis after her Rule 26(a)(2)(A) Statement had been served. NPC has moved to exclude his opinion despite the fact that plaintiff has not named him primarily because plaintiff's retained expert, Dr. Jackson, relies on Dr. Said-Al-Naief's pathology report.

² Aredia® went off patent at the end of April 2001, and generic versions of the drug entered the market. *See In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-CV-1760, 2007 WL 3012972, at *2 n.4 (M.D. Tenn. Oct. 10, 2007) (ECF No. 693). Mrs. Messick was treated with Aredia®/pamidronate therapy beginning in December 12, 2002. Health Care Record of 12/12/2002 (3778-0992) (attached as Exhibit 20). The records are ambiguous as to whether Mrs. Messick received generic pamidronate rather than brand name Aredia®: although notations in her medical records reflect both drugs, her oncologist testified that it is common practice to record Aredia® when the patient is actually receiving generic pamidronate. Deposition Transcript of Dr. Cecchi (hereinafter “Cecchi Dep.”) at 36-37 (cited excerpts attached as Exhibit 21). Although this brief refers to Aredia®, Novartis Pharmaceuticals Corporation (“NPC”) in no way concedes that Mrs. Messick received brand name Aredia® rather than generic pamidronate.

509 U.S. 579 (1993) and Federal Rule of Evidence 702.³ Dr. Jackson is not qualified to opine on the cause of Mrs. Messick's ONJ and his specific causation opinion is unreliable because his purported "methodology" for ruling out other potential risk factors as the cause of Mrs. Messick's jaw problems consists entirely of his own unsubstantiated assurances. Therefore, Dr. Jackson's opinion should be excluded in its entirety.

Causation testimony by plaintiff's treating health care providers, designated as non-retained experts, is likewise inadmissible because: (1) plaintiff failed to designate Drs. Cecchi, Fawcett, and Liautaud in her Rule 26(a)(2)(A) Statement as non-retained expert witnesses providing causation testimony, (2) plaintiff has no evidence that any of these health care providers have the necessary expertise to opine on the cause of Mrs. Messick's ONJ, (3) Drs. Fawcett and Liautaud testified that they are not experts regarding ONJ or its causes and that they are unqualified to opine on causation, and (4) to the extent that any of Mrs. Messick's health care providers even had an opinion regarding the cause of Mrs. Messick's ONJ, none employed a reliable methodology in reaching such a conclusion. As such, none of these treaters' causation testimony is admissible.

To the extent that Dr. Said-Al-Naief has a causation opinion, it is likewise inadmissible because plaintiff did not designate him as providing causation testimony in her Rule 26(a)(2)(A) Statement, Dr. Said-Al-Naief does not have the necessary expertise to opine on causation, he has admitted he is not an expert on bisphosphonate therapy or ONJ, and he admits his pathology report, for diagnostic purposes, is unreliable.

³ NPC expressly reserves the right to raise other objections to the admissibility of any testimony by these potential witnesses.

STATEMENT OF FACTS

I. LINDA MESSICK'S MEDICAL AND DENTAL HISTORY

NPC incorporates by reference the medical and dental history detailed in NPC's Memorandum in Support of Summary Judgment in the *Messick* Case and Statement of Undisputed Facts in Support of Summary Judgment in the *Messick* Case (contemporaneously filed).

II. PLAINTIFF'S DESIGNATED EXPERTS

In support of her claims, plaintiff designated Dr. Richard Jackson, an oral and maxillofacial surgeon, as a retained expert witness. Report of Dr. Richard Jackson (hereinafter "Jackson Report") (attached as Exhibit 2). In addition, plaintiff designated five of her treating physicians and dentists as non-retained experts: Dr. Gary Cecchi (oncologist), Dr. Herbert Fawcett (general dentist), Dr. Pritchard Lam (oral surgeon), Dr. Matthew Liautaud (general dentist), and Dr. Sol Silverman (oral specialist). Pl.'s Stmt at 1-2.⁴

A. Dr. Richard Jackson

Dr. Jackson examined Mrs. Messick on February 24, 2011, after her ONJ had resolved, May 10, 2011 Deposition Transcript of Dr. Richard Jackson (hereinafter "Jackson Dep. I") at 102-103 (cited excerpts attached as Exhibit 3), and submitted a four page report citing only six publications to support his opinions. *See* Jackson Report. Dr. Jackson admitted that the only literature he considered for his opinion were these six publications – all of which were published prior to 2006. Jackson Dep. I at 193-194. He admitted that he was unaware of the medical literature reporting on necrotic jaw bone exposed for over eight weeks in the absence of

⁴ Dr. Said-Al-Naief has been included in this section although he has not been designated as a non-retained expert in Plaintiff's Rule 26(a)(2)(A) statement.

bisphosphonates, *id.* at 126, and instead was basing his opinion on his clinical experience, *id.* at 125.

Dr. Jackson also reviewed less than 6% (302 out of 5,267 pages) of the medical records collected in this case by the date of his report (March 2, 2011), all of which were handpicked by Mrs. Messick's attorneys. *Id.* at 72. ("Q. Who decided what records, in terms of medical records and dental records, you would review? A. John Vecchione. Q. So the records that you received were handpicked by him, right? A. Yes."); *see* Jackson Report at 2 (noting he reviewed only the medical records for Drs. Lam, Fawcett, Liautaud, and Silverman). He did not review Mrs. Messick's oncology records nor any radiographic films. *Id.* at 65, 70-72. Because of his limited review, Dr. Jackson did not know the reason Mrs. Messick was prescribed Aredia[®] and Zometa[®] therapy: he mistakenly believed that Mrs. Messick was prescribed Aredia[®] and Zometa[®] therapy for breast cancer rather than off-label for osteoporosis. *Id.* He also based his diagnosis on an unreliable pathology report, as admitted by the pathologist himself, Dr. Said-Al Naief⁵: the pathology report was based on a three year old piece of bone that had not been properly preserved. *Id.* at 26-27, 35-36, 42; June 9, 2011 Deposition Transcript of Dr. Jackson (hereinafter "Jackson Dep. II") at 221 (cited excerpts attached as Exhibit 5). Dr. Jackson spent a total of ninety minutes reviewing the medical records and depositions prior to writing his report, Jackson Dep. I at 107, 147, and ten minutes preparing the report, *id.* at 108.

Dr. Jackson admitted that he has conducted no research on ONJ or bisphosphonate therapy, *id.* at 21, and has been involved in no clinical trials for the past seven years, *id.* at 20. He has authored no publications on ONJ or bisphosphonates and has not lectured on ONJ,

⁵ Deposition Transcript of Dr. Said-Al-Naief (hereinafter "Said-Al-Naief Dep.") at 60 (Q. Is it scientifically reliable to do a pathology now, three years after a sample is obtained, and the sample is not preserved in any way? A. For diagnostic purposes, no."); *id.* at 56-57 ("Q. As you sit here, Doctor, you have no way of knowing whether the bone

Aredia[®] or Zometa[®], or osteomyelitis. *Id.* at 20-21, 94-95. He also admitted that he is not an expert in pathology.⁶ Jackson Dep. II at 215.

Dr. Jackson did not provide an opinion that bisphosphonate therapy causes ONJ. *Id.* at 154. (“Well, the key is not the cause, the key is the support. Bisphosphonates support osteonecrosis, just like oxygen supports fire. So fire is not caused from oxygen, but it certainly is a necessary ingredient.”) And while, Dr. Jackson claims to have performed a formal differential diagnosis, he testified that he ruled out only four conditions (i.e., alveolar osteitis, osteomyelitis, osteoradionecrosis and osteonecrosis in general). Jackson Dep. II at 225. Further, Dr. Jackson agreed that Mrs. Messick presented with the following risk factors which could have contributed to her ONJ: ill-fitting dentures, Jackson Dep. I at 117-118, a tooth extraction (#28), *id.* at 120, advanced age, *id.* at 120, osteopenia and osteoporosis *id.* at 121, chemotherapy, *id.* at 123-124, corticosteroid use, *id.* at 122, and periodontal disease, *id.* at 126-127 (admitting he could not quantify the impact in terms of what percentage periodontal disease contributed to the ONJ). He testified that if multiple risk factors are present, there is no scientifically reliable way to determine which of the risk factors is the cause of the ONJ. February 13, 2008 Deposition Transcript of Dr. Jackson (hereinafter “2008 Jackson Dep.”) at 116-117 (cited excerpts attached as Exhibit 6).

B. Dr. Gary Cecchi

Dr. Cecchi was Mrs. Messick’s primary oncologist from August 2000 to the present. Health Care Record of 8/29/2000 (4220-0220-21) (attached as Exhibit 7); Cecchi Dep. at 13. He

sample that allegedly came out of Mrs. Messick’s mouth in March of 2008 was dead at the time it came out of her mouth, do you? A. No.) (cited excerpts attached as Exhibit 4).

⁶ Dr. Jackson testified that he would defer to Dr. Said-Al-Naief’s opinion regarding the pathology of Mrs. Messick’s unpreserved three year old bone sample. Jackson Dep. II at 207. Dr. Jackson sent Dr. Said-Al-Naief the bone sample without relaying to him that the bone was three years old and unpreserved, Said-Al-Naief Dep. at 41-42, which Dr. Said-Al-Naief admits renders his report unreliable in terms of a diagnosis, *id.* at 60.

has conducted no research on ONJ, *id.* at 11, has authored no articles on ONJ, *id.* at 11-12, and has taken no medical courses relating to ONJ, *id.* at 54. He was also equivocal regarding his qualifications as an expert on ONJ.

Q. As an oncologist, do you consider yourself to be qualified to make a diagnosis of osteonecrosis of the jaw?

A. Maybe.

Q. Are you familiar with the term “bisphosphonate osteonecrosis of the jaw”?

A. Yes.

Q. As an oncologist do you consider yourself qualified to render a diagnosis as to whether a patient has bisphosphonate-related osteonecrosis of the jaw?

A. Maybe.

Q. Why do you say “maybe” for ONJ and BRONJ?

A. Because based on the entire situation, consulting physicians it may be so obvious that I feel comfortable and competent to say that.

Q. Have you ever performed a differential diagnosis for osteonecrosis of the jaw, or bisphosphonate-related osteonecrosis of the jaw?

A. Sure.

Q. What are the risk factors or osteonecrosis of the jaw?

A. Is this a quiz?

Q. It is. You said “maybe,” --

A. I don't want to participate, then.....

Id. at 47-48.

Dr. Cecchi did not provide a causation opinion regarding Mrs. Messick's ONJ: he did not diagnose Mrs. Messick with ONJ or bisphosphonate-related ONJ ("BRONJ"). *Id.* at 50 ("Q. So Dr. Cecchi, did you make a diagnosis of osteonecrosis of the jaw with respect to Linda Messick? A. No. Q. Did you make a diagnosis of bisphosphonate related osteonecrosis of the jaw with respect to Linda Messick? A. No."); *see also id.* at 59 (Q. Did you ever observe anything in Linda Messick that you considered to be potentially osteonecrosis of the jaw? A. She was having a lot of jaw problems in a very complicated situation, so I wasn't going to say that she didn't have osteonecrosis of the jaw. I just wasn't going to say she did have osteonecrosis of the jaw.")

C. Dr. Herbert Fawcett

Dr. Fawcett is a general dentist who provided treatment to Mrs. Messick from June 1969 to June 2003. Transcript of Dr. Fawcett's Deposition (hereinafter "Fawcett Dep.") at 25-26, 85-86 (cited excerpts attached as Exhibit 8). Dr. Fawcett testified that he is not an expert on the topic of ONJ, *id.* at 95, and his only knowledge of the issue is based on brief internet research primarily of news articles that he conducted shortly before the deposition, *id.* at 11-13, 93. He has not published on the issue, *id.* at 17, he has never diagnosed or treated ONJ, *id.* at 19-21, and he has never taken a continuing education or professional class which discussed Aredia[®] or Zometa[®], *id.* at 95. In fact, prior to being contacted in advance of his deposition, Dr. Fawcett never heard of a possible connection between bisphosphonates and ONJ, nor had he heard of the drugs Aredia[®] and Zometa[®]. *Id.* at 19-20. Dr. Fawcett discontinued treatment before Mrs. Messick exhibited exposed bone, *see id.* at 25-26, 85-86; Health Care Record of 10/31/2005 (4458-0010) (attached as Exhibit 9); Health Care Record of 10/20/2004 (4781-0028) (attached as Exhibit 10), and did not provide a causation opinion regarding the cause of Mrs. Messick's ONJ.

D. Dr. Pritchard Lam

Dr. Lam is an oral surgeon who provided treatment to Mrs. Messick from January 1995 to November 2008. Deposition Transcript of Dr. Lam (hereinafter “Lam Dep.”) at 18 (cited excerpts attached as Exhibit 11). Since 2000, Dr. Lam has not spent time on formal research (including on ONJ). *Id.* at 7 (Q: “[S]ince the year 2000, have you spent any of your time doing research or teaching in the field of oral and maxillofacial surgery? A: No.); *see id.* at 21, 25 (conducts online research for current topics in oral surgery generally but has no research files on bisphosphonates). And, Dr. Lam has published no articles relating to ONJ. *See* Curriculum Vitae of Dr. Lam (attached as Exhibit 12).

Dr. Lam testified that there is no scientifically proven cause-and-effect relationship between bisphosphonates and ONJ, Lam Dep. at 10, 15, 110-111, and he did not render a cause-and-effect diagnosis in Mrs. Messick’s case. *See id.* at 58-59, 92 (medical record noting that the exposed bone was “possibly osteonecrosis related to bisphosphonate therapy”); *id.* at 94 (“Q: So what you formed on November 2, 2005, would you describe that as a clinical impression rather than a diagnosis? A: Correct.”); Health Care Record of 11/2/2005 (4781-0030) (attached as Exhibit 13). Because of his lack of a definitive diagnosis, he referred Mrs. Messick to Dr. Silverman. Lam Dep. at 73-75 (“Q: So when you don’t have a definitive diagnosis of your own, it’s been your habit and custom in certain circumstances to refer a patient to Dr. Silverman for his diagnosis. A: Correct. Q: And you defer to him in those circumstances. A. Yes.”); *id.* at 93.

E. Dr. Matthew Liautaud

Dr. Liautaud is a general dentist who provided treatment to Mrs. Messick from August 2003 to the present. Deposition Transcript of Dr. Liautaud (hereinafter “Liautaud Dep.”) at 15, 22 (cited excerpts attached as Exhibit 14). Dr. Liautaud testified that he is not an expert in the diagnosis of ONJ, *id.* at 17, BRONJ, *id.* at 19, and osteomyelitis, *id.* at 16. In fact, he testified

that he does not feel qualified to diagnosis these conditions in his patients, *id.* at 16-20; *see id.* at 71 (Mrs. Messick's case was the first time he had heard of a potential association between bisphosphonates and ONJ). He also testified that he is not familiar with other potential risk factors or causes of ONJ that have been identified in the scientific literature. *Id.* at 18. Dr. Liautaud admitted that he did not make an independent diagnosis of Mrs. Messick's jaw condition. *See id.* 70, 113-14.

F. Dr. Sol Silverman

Dr. Silverman is an oral medicine specialist who provided treatment to Mrs. Messick from October 5, 2004 to March 31, 2009. Deposition Transcript of Dr. Silverman (hereinafter "Silverman Dep.") at 18-19 (attached as Exhibit 15). Dr. Silverman has not conducted any research on Aredia[®], Zometa[®], ONJ, or BRONJ. *Id.* at 11-12. He has not conducted a comprehensive literature search regarding BRONJ. *Id.* at 109. And, he has no publications on BRONJ or publications focused on ONJ. *Id.* at 12.

Dr. Silverman admitted at his deposition that he did not conduct a differential diagnosis when he diagnosed Mrs. Messick with BRONJ. *Id.* at 52; 58-59, 78, 81 (noting that while he had ruled out some potential risk factors he did not rule out others such as her osteoporosis and periodontal disease). Rather, BRONJ was a "working diagnosis", *id.* at 58, bisphosphonate treatment was identified as a potential cause, *id.* at 94-96, and he merely *assumed* Mrs. Messick's condition was associated with her bisphosphonate use. *Id.* at 62 ("[t]he exposed bone, which once again we assumed from the history of intravenous bisphosphonates and just the history and how it looked, that it was probably associated"); *see id.* at 91-92 (noting if there is a history of bisphosphonate use and some type of nonhealing "then we make the assumption that there's a relationship" between the bisphosphonate therapy and ONJ).

G. Dr. Said-Al-Naief

Plaintiff requested Dr. Said-Al-Naief to perform a pathology analysis after her Rule 26(a)(2)(A) Statement had been served; in the event, plaintiff later attempts to designate Dr. Said-Al-Naief as an expert witness, NPC has included him in the current briefing.

Dr. Said-Al-Naief admitted he is not an expert in ONJ or bisphosphonate therapy. Said-Al-Naief Dep. at 36-37. He has not been involved in research involving bisphosphonate drugs or ONJ, *id.* at 34, or the possible risk factors for ONJ, *id.* at 34-35. And, he has no publications (nor submitted any manuscripts for publication) on ONJ or bisphosphonates. *Id.* at 37.

He cannot say to a reasonable degree of medical certainty whether causation between bisphosphonates and ONJ has been established. *Id.* at 21-22. He did not perform a formal differential diagnosis ruling out any of Mrs. Messick's other potential risk factors as possible causes of her ONJ. *Id.* at 54. He testified that the diagnostic portion of his pathology report is unreliable because he was unaware that the bone sample he received was three years old and had been unpreserved during that time period:

Q. Is it scientifically reliable to do a pathology now, three years after a sample is obtained, and the sample is not preserved in any way?

A. For diagnostic purposes, no.

Id. at 41-42, at 60.

ADMISSIBILITY STANDARDS UNDER DAUBERT AND RULE 702

In *Daubert*, the Supreme Court addressed the admissibility of expert testimony and established "the exacting standards of reliability such evidence must meet." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000). Plaintiffs have the burden of proving that their proposed experts' testimony is admissible under *Daubert* and its progeny. *See, e.g., Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008). First, plaintiffs must establish that the witness has the

necessary expertise, in the form of “knowledge, skill, experience, training, or education,” Fed. R. Evid. 702, to render an opinion on the specific issue addressed by his proposed testimony, *see Sigler*, 532 F.3d at 479. Second, plaintiffs must establish that the expert’s testimony is “reliable” – *i.e.*, that the testimony is “ground[ed] in the methods and procedures of science,” as opposed to the expert’s “subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 589-90 (quotation marks omitted); *see* Rule 702 (testimony must be “based upon sufficient facts or data” and “the product of reliable principles and methods” and expert witness must have “applied the principles and methods reliably to the facts of the case”). Third, plaintiffs must establish that the testimony “will assist the trier of fact in understanding and disposing of issues relevant to the case,” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000); *see* Rule 702, which means that the testimony must have “a valid scientific connection” to – *i.e.*, must “fit” – the pertinent inquiry in the lawsuit. *Daubert*, 509 U.S. at 591-92; *Pride*, 218 F.3d at 578.

Like testimony by other expert witnesses, opinion testimony by a treating physician must satisfy the *Daubert* admissibility standards. *See Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009); *O’Conner v. Commw. Edison Co.*, 13 F.3d 1090, 1105 n.14 (7th Cir. 1994); *see also Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (“A treating physician’s expert opinion on causation is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for purposes of litigation.” (quotation marks omitted)).

Applying *Daubert*, this Court excluded causation testimony of other plaintiffs’ non-retained experts in three Wave I-A cases. *See In re Aredia & Zometa Prods. Liab. Litig.* (*Anderson v. NPC*), No. 3:06-md-1760, 2009 WL 2496927 (M.D. Tenn. Aug. 13, 2009) (ECF No. 2803) (excluding causation testimony of plaintiff’s non-retained experts who admittedly

lacked the expertise needed to opine that Zometa[®] caused the patient's ONJ and/or did not offer such opinion to a reasonable degree of medical certainty); *In re Aredia & Zometa Prods. Liab. Litig. (Melau v. NPC)*, No. 3:06-md-1760, 2009 WL 2496921 (M.D. Tenn. Aug. 13, 2009) (ECF No. 2807) (same); *In re Aredia & Zometa Prods. Liab. Litig. (Thomas v. NPC)*, No. 3:06-md-1760, 2009 WL 2584828 (M.D. Tenn. Aug. 13, 2009) (ECF No. 2771) (same). In reaching its conclusions, the Court held that "a treating physician's testimony remains subject to the requirement[s] set forth in *Daubert*." *Anderson*, 2009 WL 2496927, at *1 (citing *Gass*, 558 F.3d at 426 (6th Cir. 2009)). The Court similarly recognized that "a treating physician's expert opinion on causation is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation," *id.* (citing *Bland*, 538 F.3d at 897), and stated that "there is a fundamental distinction between a treating physician's ability to render a medical diagnosis based on clinical experience and her ability to render an opinion on causation of the plaintiff's injuries" because the latter requires "the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions," *id.* at *2 (citing *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1211 (E.D. Tenn. 2000)).

ARGUMENT

I. PLAINTIFF FAILED TO DESIGNATE DR. CECCHI, DR. FAWCETT, DR. LIAUTAUD, AND DR. SAID-AL-NAIEF IN HER RULE 26(a)(2)(A) STATEMENT AS NON-RETAINED EXPERT WITNESSES PROVIDING CAUSATION TESTIMONY

If plaintiff had wished to offer causation opinions from Drs. Cecchi, Fawcett, Liautaud, and Said-Al-Naief, she was required to designate these individuals on this subject. Although the Agreed Order Regarding Disclosures of Non-Retained Expert Witnesses (ECF No. 2040) applied explicitly only to Wave I-A, both plaintiffs and NPC have continued to observe its requirements

in their disclosures of such experts. *See e.g.*, Pl’s Stmt at 1. The Agreed Order requires that parties “state the issue(s) regarding which the disclosing party may elicit testimony from the witness at trial.” Agreed Order ¶ 1(d). Plaintiff, however, did not state that she intends to elicit causation testimony from these treaters. Because plaintiff has failed to appropriately designate these treaters as non-retained experts on the issue of specific causation, the Court should preclude them from offering causation testimony at the outset with any need to reference the argument set forth below. That argument will confirm, however, that none should be permitted to testify.

II. NONE OF THE DESIGNATED EXPERTS IS QUALIFIED TO OPINE ON THE CAUSE OF MRS. MESSICK’S ONJ.

A. Mrs. Messick’s Retained Expert - Dr. Jackson

Although NPC does not challenge Dr. Jackson’s ability to diagnose the existence of ONJ or to treat patients in a clinical setting, he is not qualified to opine as to whether Aredia[®] or Zometa[®] can cause ONJ or whether it caused Mrs. Messick’s ONJ. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010), *cert. denied*, 79 U.S.L.W. 3554 (2011) (emphasizing the distinction between diagnosing an injury or disease and determining its cause or etiology); *Gass*, 558 F.3d at 426-28 (same); *Anderson*, 2009 WL 2496927 (same); *Wynacht*, 113 F. Supp. 2d at 1209 (“The ability to diagnose medical conditions is not remotely the same, however, as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions.”).

Dr. Jackson’s opinion appears to be based on his limited clinical experience. *E.g.*, Jackson Dep. I at 125-126 (acknowledging that he was not aware of the medical literature reporting on necrotic jaw bone exposed for over eight weeks in the absence of bisphosphonates and was basing his opinion on his clinical experience). This is what he primarily relies upon to

support of his opinions, but it is not sufficient from a legal standpoint. *Chapman v. Maytag Corp.*, 297 F.3d 682, 688 (7th Cir. 2002) (“[p]ersonal observation is not a substitute for scientific methodology and is insufficient to satisfy *Daubert*’s most significant guidepost”); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1372 (N.D. Ga. 2001) (“Doctors in their day-to-day practices stumble upon coincidental occurrences and random events and often follow human nature, which is to confuse association and causation.”); *see also Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1196 (11th Cir. 2002) (noting that the district court in *Siharath* “drew a careful distinction between the clinical process, in which conclusions must be extrapolated from incomplete data, and the scientific method, in which conclusions must be drawn from an accepted process....”); *O’Conner*, 13 F.3d at 1107 n. 19 (finding that treating physician’s limited experience with subject of his testimony did not qualify “as a basis for a scientifically sound opinion”).

Dr. Jackson’s testimony demonstrates his lack of requisite expertise in determining the etiology of ONJ: he has conducted no research, Jackson Dep. I at 21, has authored no publications on ONJ or bisphosphonates, and has not lectured on ONJ, Aredia[®] or Zometa[®], or osteomyelitis, *id.* at 20-21, 94-95. Without expertise in any of these areas, Dr. Jackson cannot be qualified to opine that bisphosphonates can cause ONJ or what, in fact, caused Mrs. Messick’s ONJ. His analysis is a classic case of a clinician incorrectly conflating his diagnosis with the unreliability of his causation assessment. *Tamraz*, 620 F.3d at 674 (noting that diagnosis and etiology are two different types of expertise and “the reliability of one does not guarantee the reliability of the other”). Because Dr. Jackson lacks the requisite “knowledge, skill, experience, training, or education,” he is not qualified to opine on causation in this case. *See Fed. R. Evid.* 702; *Sigler*, 532 F.3d at 479.

B. Mrs. Messick's Non-retained Experts⁷

Plaintiff's health care providers and Dr. Said-Al-Naief are subject to the same rigorous admissibility analysis under Rule 702 and *Daubert* as retained expert witnesses. *Anderson*, 2009 WL 2496927 (excluding causation testimony of plaintiff's non-retained experts who admittedly lacked the expertise needed to opine that Zometa[®] caused the patient's ONJ and/or did not offer such opinion to a reasonable degree of medical certainty); *Melau*, 2009 WL 2496921 (same); *Thomas*, 2009 WL 2584828 (same); *O'Conner*, 13 F.3d at 1105 n.14 ("[W]e do not distinguish the treating physician from other experts when the treating physician is offering expert testimony regarding causation"). Mrs. Messick has not provided evidence that any of her health care providers or Dr. Said-Al-Naief are qualified to opine on the cause of her ONJ.

With respect to Drs. Cecchi, Lam and Silverman, none can qualify as an expert entitled to offer opinions because none has taken the necessary step of conducting research on the topic of BRONJ or ONJ. Cecchi Dep. at 11; Lam Dep. at 7, 21, 25; Curriculum Vitae of Dr. Lam; Silverman Dep. at 11-12, 109. Further, Dr. Cecchi has authored no article nor taken any medical course relating to ONJ. Cecchi Dep. at 11-12, 54. Because Drs. Cecchi, Lam, and Silverman lack the requisite "knowledge, skill, experience, training, or education," they are not qualified to opine on causation in this case. *See* Fed. R. Evid. 702; *Sigler*, 532 F.3d at 479.

Drs. Fawcett and Liautaud unequivocally admitted that they are not experts on the causes of ONJ. Fawcett Dep. at 95; Liautaud Dep. at 16-20, 71. Dr. Said-Al-Naief also admitted that he is not an expert on ONJ or bisphosphonate therapy. Said-Al-Naief Dep. at 36-37. This Court has concluded that other plaintiffs had not met their burden of demonstrating the admissibility of causation testimony of non-retained experts in several cases in part because the treating

⁷ Dr. Said-Al-Naief has been included in this subheading although he has not been designated as a non-retained expert in Plaintiff's Rule 26(a)(2)(A) statement.

physicians testified that they lacked the necessary expertise. *See, e.g., Melau*, 2009 WL 2496921 (“If an expert is not qualified to opine in a particular area, and [that expert] admits that he is not qualified to provide opinions about ONJ, such testimony is excluded under *Daubert*.”) (citing *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1047 (D. Minn. 2007); *Thomas*, 2009 WL 2584828 at *3 (“Dr. Johnson has admitted that he is not an expert with regard to ONJ. . . . As the court stated in *Gass*, the ability to diagnose medical conditions is not the same as the ability to opine as an expert about the specific causes of those conditions. Plaintiff has not carried his burden to show that Dr. Johnson’s medical expertise provides a basis for determining the exact cause or mechanism by which Plaintiff developed ONJ.”) (citing *Gass*, 558 F.3d at 428); *In re Aredia & Zometa Prods. Liab. Litig. (McDaniel v. NPC)*, No. 3:06-md-1760, 2010 WL 5136138 at *3 (M.D. Tenn. Dec. 7, 2010) (ECF No. 4048) (“Dr. Brandebura, by his own admission, is not an expert on ONJ or the causes of ONJ. . . . Therefore, Dr. Brandebura cannot offer admissible expert testimony on causation in this case.”); *In re Aredia & Zometa Prods. Liab. Litig. (Calloway/Shewmake v. NPC)*, No. 3:06-md-1760, 2010 WL 4970987 at *3 (M.D. Tenn. Dec. 7, 2010) (ECF No. 4062) (“The Court finds that neither Dr. Montgomery nor Dr. West is qualified, by their own admission, to offer expert testimony on the specific cause of Mrs. Calloway’s ONJ.”). *See also, e.g., Baycol*, 532 F. Supp. 2d at 1047 (“If an expert is not qualified to opine in a particular area, and Dr. Mayer admits he is not qualified to provide opinions about a drug’s comparative safety, such testimony is excluded under *Daubert*.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 559 (S.D.N.Y. 2004) (“In view of Dr. Bell’s admitted lack of pertinent expertise, the testimony is excluded.”).⁸ Thus, these health care

⁸ *See also Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 611 (7th Cir. 2002) (affirming exclusion of expert testimony when purported expert admitted at his deposition that he was not an expert in the areas of modeling he relied on to form his conclusion); *Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co.*, 958 F.2d 1169, 1174-75 (1st Cir. 1992) (affirming exclusion of expert testimony regarding cranes and crane safety because, *inter alia*, expert

providers and Dr. Said-Al-Naief are unqualified and the Court should exclude any testimony from these providers at trial regarding the cause of Mrs. Messick's ONJ.

III. PLAINTIFF'S EXPERTS' SPECIFIC CAUSATION OPINIONS ARE UNRELIABLE AND INADMISSIBLE UNDER *DAUBERT*

Where a plaintiff seeks to admit an expert opinion on specific causation, the Sixth Circuit has held that a reliable differential diagnosis requires both that a doctor “‘rule[s] in’ the suspected cause . . . using scientifically valid methodology” and then that the doctor engage in “standard diagnostic techniques by which doctors normally rule out alternative causes.” *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179-80 (6th Cir. 2009); *see also id.* at 178 (“[t]he physician considers *all relevant potential causes* of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and *a thorough case history*.” (citing Federal Judicial Center, Reference Manual on Scientific Evidence 214 (1994)) (emphasis added). In other words, a court looks for “methodological rigor.” *See Best*, 563 F.3d at 179 (quoting *Rolen v. Hansen Beverage Co.*, 193 F. App'x 468, 474 n.4 (6th Cir. 2006)). A doctor's claim that he performed a differential diagnosis is necessary, but not sufficient, to establish the reliability of the doctor's technique. *Tamraz*, 620 F.3d at 674; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005). The Sixth Circuit recently reaffirmed this Court's cautious approach to admitting a physician's expert testimony in *Tamraz* 620 F.3d at 676-78. *Tamraz*

“testified that he was not an expert in either load moment indicators or crane operation”); *Long v. Monaco Coach Corp.*, No. 3:04-CV-203, 2007 WL 4613000, at *5-6 (E.D. Tenn. Sept. 27, 2007) (excluding expert offered to value motor coaches who “testified repeatedly that he was not an expert in the field of valuation”) (attached as Exhibit 16); *Memphis-Shelby County Airport Auth. v. Ill. Valley Paving Co.*, No. 01-3041 B/An, 2006 WL 5981486, at *3-4 (W.D. Tenn. July 21, 2006) (holding that purported expert in underground cables used in an airport construction project was not qualified to testify because, *inter alia*, expert testified he was not an expert in chemistry, polymers, or co-polymers, which were used in the cables at issue) (attached as Exhibit 17); *Wal-Mart Stores, Inc. v. Qore, Inc.*, No. 1:06CV326, 2009 WL 305801, at *2-3 (N.D. Miss. Feb. 3, 2009) (striking expert's calculations distinguishing betterments from remediation work when expert testified he was not an expert in this area) (attached as Exhibit 18); *Francois v. Colonial Freight Sys., Inc.*, No. 3:06-cv-434-WHB-LRA, 2008 WL 80399, at *2-3 (S.D. Miss. Jan. 4, 2008) (limiting expert's opinions to clinical psychology and not neuropsychology when expert testified he was not an expert in the field of neuropsychology) (attached as Exhibit 19).

emphasized the distinction between diagnosing an injury or disease and determining its cause or etiology, *id.* at 672-74.

A. Dr. Jackson's Specific Causation Opinions Must Be Excluded as Unreliable Because His Differential Diagnosis Employed an Improper Methodology

Dr. Jackson did not provide an opinion that bisphosphonate therapy causes ONJ. Jackson Dep. I at 154 (“Well, the key is not the cause, the key is the support. Bisphosphonates support osteonecrosis, just like oxygen supports fire. So fire is not caused from oxygen, but it certainly is a necessary ingredient.”). When the outcome of the analysis is a foregone conclusion, as it is with Dr. Jackson, regardless of medical or scientific evidence to the contrary, the resulting opinion must be excluded under *Daubert*. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”). *Daubert* requires that the expert’s testimony be “reliable,” in that the testimony is “ground[ed] in the methods and procedures of science,” as opposed to the expert’s “subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 589-90 (quotation marks omitted). Dr. Jackson’s opinions regarding causation are nothing more than assumptions, and his noncommittal testimony on general causation (i.e., whether bisphosphonate can cause ONJ) confirms that his opinions are inadmissible. *See, e.g., Grimes v. Hoffmann-LaRoche, Inc.*, 907 F. Supp. 33, 38 (D.N.H. 1995) (“Since [expert’s] opinion on specific causation is necessarily based on his opinion concerning general causation, that testimony must be excluded as well.”).

Although, Dr. Jackson claims to have performed a differential diagnosis, “simply claiming that an expert used the ‘differential diagnosis’ method is not some incantation that opens the *Daubert* gate.” *Tamraz*, 620 F.3d at 674. Dr. Jackson reviewed an extremely narrow amount (< 6%) of the plaintiff’s medical records collected in this case by the date of his report

(March 2, 2011). *See* Jackson Report at 2. Because of his limited review, Dr. Jackson failed to review medical records of some dental care providers who treated plaintiff in the 2003-2004 timeframe. And, he did not know the reason Mrs. Messick was prescribed Aredia[®] and Zometa[®] therapy: he mistakenly assumed that Mrs. Messick was prescribed Aredia[®] and Zometa[®] therapy for breast cancer rather than osteoporosis. Jackson Dep. I at 65, 70-72. He further testified that he ruled out only four conditions as part of his differential diagnosis (i.e., alveolar osteitis, osteomyelitis, osteoradionecrosis and osteonecrosis in general), Jackson Dep. II at 225. Dr. Jackson agreed that Mrs. Messick presented with multiple risk factors (e.g., ill fitting dentures, osteoporosis) which could have contributed to her ONJ, Jackson Dep. I at 117-118, 121. And he previously testified that if multiple risk factors are present, there is no scientifically reliable way to determine which of the risk factors is the cause of the ONJ. 2008 Jackson Dep. at 116-117.

Dr. Jackson's complete failure to conduct a scientifically-based differential diagnosis and utilize a reliable scientific methodology demonstrates that his opinions are simply *ipse dixit* and not conclusions grounded in science. *Gen. Elec.*, 522 U.S. at 146. When an expert cannot rule out alternative causes of an alleged injury, his opinion is inadmissible under *Daubert*'s reliability prong. *Best*, 563 F.3d at 179-80; *see also Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999) (“[W]here a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that it was not the sole cause, that doctor's methodology is unreliable.” (quoting *In re Paoli R.R. PCP Litig.*, 35 F.3d 717, 759 n.27) (3d Cir. 1994); *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994) (excluding causation opinions because experts were “unable to exclude other potential causes for [the plaintiffs'] symptoms”). Dr. Jackson's failure to reliably rule out ill-fitting dentures and Mrs. Messick's numerous other risk factors for ONJ, such as periodontitis, tooth extraction, and/or

chemotherapy, or to offer any valid explanation whatsoever as to why these things – and not Aredia[®] or Zometa[®] – were the cause of Mrs. Messick's ONJ renders his differential diagnosis unreliable. As such, his causation opinion is inadmissible.

B. Plaintiff Cannot Demonstrate That Any Opinions Mrs. Messick's Designated Health Care Providers or Dr. Said-Al-Naief May Have Regarding the Cause of Her Osteonecrosis Satisfy *Daubert's* Reliability Requirement

To the extent that any of Mrs. Messick's health care providers or Dr. Said-Al-Naief even had an opinion regarding the cause of her jaw problem, none performed a differential diagnosis or other reliable methodology to determine the cause.

Dr. Fawcett, Dr. Liautaud, and Dr. Cecchi did not offer a causation opinion. Dr. Fawcett discontinued treatment before Mrs. Messick had exposed bone, *see* Health Care Record of 10/31/2005 (4458-0010); Health Care Record of 10/20/2004 (4781-0028), and did not provide a causation opinion regarding the cause of Mrs. Messick's ONJ. Dr. Liautaud admitted that he did not make an independent diagnosis of Mrs. Messick's jaw condition. Liautaud Dep. at 70, 113-14. And Dr. Cecchi did not diagnosis Mrs. Messick with ONJ or BRONJ. *Id.* at 49-50.

Dr. Lam, Dr. Silverman, and Dr. Said-Al-Naief did not conduct a reliable differential diagnosis to determine the cause of Mrs. Messick's ONJ. Dr. Lam testified that there is no scientifically proven cause-and-effect relationship between bisphosphonates and ONJ, Lam Dep. at 10, 15, 110-111, and that he did not render a cause-and-effect diagnosis in Mrs. Messick's case. *Id.* at 58-59, 92, 94. Because of his lack of a definitive diagnosis, he testified that he deferred to Dr. Silverman. Lam Dep. at 73-75 ("Q: So when you don't have a definitive diagnosis of your own, it's been your habit and custom in certain circumstances to refer a patient to Dr. Silverman for his diagnosis. A: Correct. Q: And you defer to him in those circumstances. A. Yes."), *id.* at 93.

Dr. Silverman admitted that he did not conduct a differential diagnosis when he diagnosed Mrs. Messick with BRONJ. Silverman Dep. at 52; 58-59, 78, 81 (noting that while he had ruled out some potential risk factors he did not rule out others such as her osteoporosis and periodontal disease). Rather, BRONJ was a “working diagnosis,” *id.* at 58, bisphosphonate treatment was identified as a potential cause, *id.* at 94-96, and he had *assumed* Mrs. Messick’s condition was associated with her bisphosphonate use. *Id.* at 62, 91-92.

Dr. Said-Al-Naief cannot say to a reasonable degree of medical certainty whether causation between bisphosphonates and ONJ has been established. Said-al-Naief Dep. at 21-22. He did not perform a formal differential diagnosis ruling out any of Mrs. Messick’s other potential risk factors as possible causes of her ONJ. *Id.* at 54. And he testified that the diagnostic portion of his pathology report is unreliable because he was unaware that the bone sample he received was three years old and had been unpreserved during that time period. *Id.* at 41-42, at 60.

As noted above, when an expert cannot rule out alternative causes of an alleged injury, the expert’s differential diagnosis violates *Daubert*’s reliability prong. *Best*, 563 F.3d at 179-80; *see also Heller*, 167 F.3d at 156. Neither Mrs. Messick’s treating physicians nor Dr. Said-Al-Naief reliably ruled out alternative causes of Mr. Messick’s ONJ. Accordingly, each should be precluded from offering expert testimony.

CONCLUSION

For the foregoing reasons, the Court should exclude causation testimony from all of the above-named designated experts and Dr. Said-Al-Naief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 13th day of June 2011 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's Memorandum of Law in Support of *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Experts in the *Messick* Case by operation of the Court's Electronic Case Filing System on the following, including Plaintiff's

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